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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,287	09/24/2003	Gary Karlin Michelson	101.0092-02000	6591
22882	7590	12/14/2005	EXAMINER	
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			BARRETT, THOMAS C	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/669,287	MICHELSON, GARY KARLIN	
	Examiner	Art Unit	
	Thomas C. Barrett	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 September 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-96 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-96 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-05-10-05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### **REQUEST FOR CONTINUED EXAMINATION**

The request filed on September 19, 2005 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/669,287 is acceptable and a RCE has been established. An action on the RCE follows.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on 19, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,793,679 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-96 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argues "The only insertion position taught by Nolan is one in which the implant is cylindrical-shaped. No other insertion position is taught." As noted in prior actions, col. 4 lines 21-23 of Nolan discloses that widths 26 and 28 in figure 3 can be of different sizes, which would therefore make the implant frusto-conical in shape.

The Applicant also argues, "Nolan does not teach or suggest a bone-engaging projection adapted for linear insertion." Nolan discloses, "The body can have an outer

surface with a radial projection or more preferably, a plurality of radial projections extending therefrom such as in the form of threads" (col. 2, lines 43-47). Therefore the radial projections of Nolan are not necessarily threads.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-72, 74-76 and 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (6,117,174) in view of Michelson (5,785,710) as cited in Applicant's IDS. Nolan discloses an expansile spinal fusion implant with a portion of a frusto-conical shape and an expanding disc (Fig. 17). The implant can be cylindrical or frusto-conical in its unexpanded position. Col. 4 lines 21-23 discloses that widths 26 and 28 in figure 3 can be of different sizes, therefore the shape may be frusto-conical. The implant comprises radial bone-engaging projections. However Nolan does not disclose the radial projections as "adapted for linear insertion". Michelson teaches a fusion implant with radial projections adapted for linear insertion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of radial projections adapted for linear insertion, as taught by Michelson, to an expansile spinal fusion implant as per Nolan, in order to "urge the spinal fusion implant

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forward against the solid unremoved bone further resisting dislodgement and controlling motion resulting in an exceedingly stable implantation" (Michelson-col. 9, lines 23-39).

Claims 73 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (6,117,174) in view of Michelson (5,785,710) as above, in further view of Ray et al. (4,961,740). Nolan modified by Michelson discloses an expandable spinal fusion implant however fails to disclose the use of hydroxyapatite as a material for the implant. Ray et al. teaches the use of hydroxyapatite as a material for a spinal fusion implant, which is useful as a bone-inducing substance (col. 4, lines 46-56). It would have been obvious to one of ordinary skill in the art to combine the teaching of hydroxyapatite as a material for a spinal fusion implant, as taught by Ray et al., to the spinal fusion implant as per Nolan/ Michelson, which is useful as a bone-inducing substance. Also Nolan/ Michelson fails to disclose the use of a snap fit cap for the ends of the implant. Ray et al. teaches the use of snap-fit caps for the ends of the implant (col. 6, line 56) to retain bone-inducing substance when it is packed into the implant (col. 4, lines 20-23). It would have been obvious to one of ordinary skill in the art to combine the teaching of snap-fit caps for the ends of the implant, as taught by Ray et al., to the spinal fusion implant as per Nolan/ Michelson, to retain bone-inducing substance when it is packed into the implant.

Claims 77-83 and 89-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (6,117,174) in view of Michelson (5,785,710) as above, in further view of what would be obvious to one of ordinary skill in the art. Nolan modified by Michelson discloses an expandable spinal fusion implant however Nolan fails to

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disclose the use of bone, genes coding or bone morphogenetic protein as a material for the implant. It is well known to one of ordinary skill in the art to use bone, genes coding or bone morphogenetic protein as a material for a spinal fusion implant, to induce bone ingrowth into the implant. It would have been obvious to one of ordinary skill in the art to combine the teaching of bone, genes coding or bone morphogenetic protein as a material for a spinal fusion implant, as is well known in the art, to the spinal fusion implant as per Nolan/ Michelson, to induce bone ingrowth into the implant.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Thomas Barrett  
Examiner  
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